REMARKS

This is in response to the Office Action dated 4/09/2003. With this Amendment, claims 3-4, 8 and10 are amended and claims 11-14 are added so that claims 3-6 and 8-14 are now pending in this Application.

35 U.S.C. § 112

The Examiner rejected claims 3-6 and 8-10 under 35 U.S.C. § 112, first paragraph, because the specification does not sufficiently enable one of skill in the are to make and use the invention commensurate in scope with the claims. In response to the Examiner's rejection, claims 3, 4, 8 and 10 have been amended to limit the scope of the claims to that commensurate with the specification. Claims 5-6 and 9 are dependent upon claims 3, 4, and 8 respectively are thus also so limited.

Claims 11 and 12 are new claims dependent upon claim 3 that further define the peptide subject matter of claim 3. New independent claim 13 and dependent claim 14 are also directed to the peptide of the present invention. The subject matter of claims 13 and 14 is sufficiently similar to that of the currently pending claims such that the arguments presented and accepted by the Examiner in the Amendment filed March 11, 2003 are also applicable to claims 13 and 14.

35 U.S.C. § 103

The Examiner rejected claim 3 under as being unpatentable over Harris et al. in combination with the teachings of Sambrook. The Examiner asserts it would have been obvious at the time of the invention to produce an isolate polypeptide consisting of only the extracellular domain of EPO receptor, by genetically engineering expression systems that incorporate cDNA that encodes only the extracelluar domain of human EPO receptor, using the methods taught by Sambrook et al. because of the utility suggested by Harris.

The Examiner's assertion of obviousness is unsupported. The vague and overly generalized suggestions of Sambrook do not enable one to successfully express and isolate a chosen peptide. Sambrook fails to provide any specific teachings to assist one in skill in the art of producing the EPO extracelluar domain of claims 3 and 11-14. In fact, Sambrook acknowledges the inherent difficulty in producing functional eukaryotic proteins on page 16.3:

> A **few** eukaryotic proteins have been expressed efficiently and inexpensively in prokaryotic hosts (see Chapter 17). However, **many** eukaryotic proteins synthesized in bacteria **fold incorrectly or inefficiently** and, consequently, exhibit low specific activities.

(emphasis added). While cloning of DNA into vectors for expression in foreign hosts can be modeled for laymen in terms of a simple combining of pieces, the systems are in reality much more complex and any expression of functional protein is far from guaranteed. Those of skill in the art have since realized that protein expression is a difficult proposition often requiring experimentation.

The fact that Harris fails to produce a free EPO extracelluar domain is evidence that the production of a free extracellular domain of EPO receptor was not obvious to one of skill in the art at the time of invention. Harris describes his expressed protein in the middle of the first column on page 15206 as "The bulk of the EREx protein is found in the insoluble pellet in a nonfunctional form." Harris was not successful in cleaving what little functional fusion protein that he obtained and therefore failed to separate and purify a functional EPO extracellular domain from the fusion protein. In additional support of this point, a declaration by the inventor of the present application having repeated the work of Harris demonstrating the failure to cleave is submitted with this Amendment. The declaration was previously submitted in the related prosecution of application 08/850,293 resulting in U.S. Patent No. 5,843,726. The present application is a divisional of parent U.S. Application Serial No. 08/106,815, filed August 16, 1993 resulting in the '726 patent.

Sequence Submission

A sequence submission is submitted to comply with 37 C.F.R. § 1.821 through 1.825. A review of the file wrapper has shown that no sequence submission has been previously accepted in the present application, although required by sequences present in the specification. Although the Examiner did not include a Notice to Comply with sequence requirements in the Office Action, that objection was made previously during the prosecution of this application. Two sequences explicitly disclosed in the Specification on page 14 and a third on page 19 are included in this sequence listing, therefore no new matter is introduced.

Additionally, the DNA sequence coding for the EPO receptor protein of LAP 37, used in the present invention as described on pages 13-14, is included in the sequence submission. The DNA sequence coding for the EPO receptor protein is published in Winkelmann, John C., Laura A. Penny, Larry L. Deaven, Bernard G. Forget, and Robert B. Jenkins, *The Gene for the Human Erythropoietin Receptor: Analysis of the Coding Sequence and Assignment to Chromosome 19p*, Blood, Vol. 76, No. 1 (July 1), 1990, pages 24-30. The article was cited in the specification on page 2.

Paragraphs requiring added SEQ ID No. information have been replaced. In addition, the paragraph on page 14 misidentified the amino acid numbers as counted on full length Epo R. The PCR product is correctly identified as extending through amino acid 250 elsewhere in the application, for example on page 10. Therefore, the numbers of the paragraph on page 14 are requested to be replaced.

Request for Interview

With the changes to the claims in the present Amendment, Application respectfully submits that the present application is in condition for allowance. However, if the Examiner believes that further action is required for allowance of the Application, a telephone interview is requested. Please contact Anne M. Murphy, Reg. No. P54,327 at 612-337-9371. An Associate Power of Attorney is enclosed.

Respectfully submitted,

KINNEY & LANGE, P.A.

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By _____

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